UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/676,694	09/30/2003	Michael Brines	10165-027-999	7980

7590 02/26/2008

FREDERICK J. HAMBLE, ESQ.
712 KITCHAWAN ROAD
OSSINING, NY 10562

EXAMINER	
LI, RUIXIANG	
ART UNIT	PAPER NUMBER
1646	
MAIL DATE	DELIVERY MODE
02/26/2008	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/676,694	BRINES ET AL.	
	Examiner	Art Unit	
	RUIXIANG LI	1646	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *30 November 2007*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *13,14,16-21,31,32 and 43-50* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *13, 14, 16-21, 31, 32, and 43-50* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Status of Application, Amendments, and/or Claims

Applicants' amendment filed on 11/30/2007 has been entered in full. Claims 1-12, 15, 22-30, and 33-42 are canceled. Claims 13, 16, 17, 19, 20, 31, 32, and 43-50 are amended. Claims 13, 14, 16-21, 31, 32, and 43-50 are pending and under consideration.

Withdrawn Objections and/or Rejections

The objection to the disclosure is withdrawn in view of amended specification.

The objection to claims 16-20, 29-32, and 43-50 for depending from non-elected claims is withdrawn in view of amended claims.

Claim Rejections Under 35 U.S.C. §112, 1st Paragraph

(i). The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

(ii). Claims 13, 14, 16-21, 31, 32, and 43-50 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a method of using a tissue protective cytokine receptor complex comprising an EPO receptor and/or a βc in screening assays to identify a compound that exhibit a tissue protective activity, does

not reasonably provide enablement for a method of using any other tissue protective cytokine receptor complexes in screening assays to identify a compound that exhibit a tissue protective activity. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to use the invention commensurate in scope with these claims. The scope of enablement rejection has been changed in response to applicants' argument (see below).

(iii). Response to Applicants' argument

Beginning at page 7 of Applicants' response filed on 11/30/2007, Applicants cite case law and review the test for enablement, with which the examiner takes no issue.

Beginning at the bottom of page 8 of Applicants' response filed on 11/30/2007, Applicants argue that the specification and the prior art describes various tissue protective cytokine receptor complex comprising an EPO receptor and/or βc receptor. The Examiner agrees. However, neither the specification nor the prior art teaches a method of using a tissue protective cytokine receptor complex other than one comprising an EPO receptor and/or a βc in screening assays to identify a compound that exhibit a tissue protective activity. Thus, the specification, while being enabling for a method of using a tissue protective cytokine receptor complex comprising an EPO receptor and/or a βc in screening assays to identify a compound that exhibit a tissue protective activity, does not reasonably provide enablement for a method of using any

other tissue protective cytokine receptor complexes in screening assays to identify a compound that exhibit a tissue protective activity.

Claim Rejections under 35 USC§ 112, 2nd paragraph

(i). The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

(ii). Claims 13, 14, 16-20, 31, 32, 43-50 are rejected under 35 U.S.C. §112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 13 is indefinite because the step (c) recites "assaying the identified test compound for a tissue protective activity", but fails to point out how to assay the identified test compound for a tissue protective activity and what tissue protective activity is determined. Claims 14, 16-20, 31, 32, and 43-50 are rejected as dependent claims from claim 13.

At page 10, the 3rd paragraph of Applicants' response, Applicants argue that the specification as filed clearly describes the identification of the compounds having tissue protective activity by use of assays that measure reporter gene activity in a host cell. This is not found to be persuasive because claim 13, as written, recites "assaying *the*

identified test compound for a tissue protective activity", but fails to point out how to assay the identified test compound for a tissue protective activity and what tissue protective activity is determined.

Claim Rejections Under 35 U. S. C. § 103 (a)

(i). The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

(ii). Claims 13, 14, 17, 19, 20, 48, and 49 are rejected under 35 U.S.C. 103(a) as being unpatentable over Jubinsky et al. (Blood 90:1867-1873, 1997) in view of Mercury™ Pathway Profiling System User Manual (Clontech, March 2, 2001). The rejection is on the basis set forth in the office action mailed on 05/31/2007.

Claims 13, 16-18, 21, and 43-48, and 50 are rejected under 35 U.S.C. 103(a) as being unpatentable over Jubinsky et al. (Blood 90:1867-1873, 1997) in view of Trueheart et al. (U.S. Patent No: 6159705, December 12, 2000). The rejection is on the basis set forth in the office action mailed on 05/31/2007.

(iii). Response to Applicants' argument

Beginning at page 11 of Applicants' response filed on 11/30/2007, Applicants cite case law and review the legal standard for obviousness, with which the examiner takes no issue.

Beginning at page 14 of Applicants' response, Applicants summarize the claimed invention and argue that Jubinsky only examines the role of the EPO-R/βc receptor complex in cellular proliferation and never contemplates or suggests a tissue protective role for this receptor complex and that nowhere does Jubinsky suggest a tissue protective activity mediated by the EPO-R/βc receptor complex.

Applicants' argument has been fully considered, but is not deemed to be persuasive because Jubinsky et al. teach, among others, that at Ba/F3-EPO-R+βc required EPO for survival and responded to EPO (see, e.g., bottom of right column of page 1868; Fig. 1) and a functional role of βc in the EPO-dependent proliferation of Ba/F3 cells that express EPO-R. Therefore, Jubinsky et al. teach a tissue protective role for a functional complex comprising EPO receptor (EPO-R) and a common β chain (βc) in murine Ba/F3 cells (see specification at paragraphs [0006], [0091], [0037]).

Beginning at the bottom of page 15 of Applicants' response, Applicants argue that the results disclosed in the instant application concerning the unexpected pathway for signalling of tissue protective cytokine activity through the EPO-R/βc receptor complex

was completely unexpected based on the teachings of Jubinsky and others at the time of the presently claimed invention.

Applicants' argument has been fully considered, but is not deemed to be persuasive for the following reasons. First, the instantly claimed invention is drawn to a cell-based screening method for identifying a compound that modulates a tissue activity using a tissue protective cytokine receptor complex-expressing cell. The claims do not recite any particular tissue protective receptor complex or any particular signal transduction pathway.

Second, Jubinsky et al. teach that Ba/F3-EPO-R+βc required EPO for survival and responded to EPO (see, e.g., bottom of right column of page 1868; Fig. 1) and a functional role of βc in the EPO-dependent proliferation of Ba/F3 cells that express EPO-R. Jubinsky et al. teach a method for identifying the effect of antisense to βc, sense, and nonsense on EPO-dependent proliferation and β globin expression in Ba/F3 cells (page 1869; Fig. 2). Thus, Jubinsky et al. teach a cell system that can be used to identify a compound that modulates the activity of EPO-R/βc in BaF3 cells.

Furthermore, Jubinsky et al. do not teach away from the claimed invention. Jubinsky et al. interpret the results on mice performed by others, discuss the possibility that EPO interacts with the non-disrupt chain, and explain why both Nishinakamura and Stanley saw no change in the test animals' responsiveness to EPO despite the lack of either βc

or βIL-3 receptor gene. Thus, Jubinsky et al. do not teach away from a cell system that can be used to identify a compound that modulates the activity of EPO-R/βc in BaF3 cells.

Conclusion

No claims are allowed.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Advisory Information

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ruixiang Li whose telephone number is (571) 272-0875. The examiner can normally be reached on Monday through Friday from 8:30 am to 5:00

pm. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Nickol, can be reached on (571) 272-0835. The fax number for the organization where this application or proceeding is assigned is (571) 273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, please contact the Electronic Business Center (EBC) at the toll-free phone number 866-217-9197.

/Ruixiang Li/
Primary Examiner, Art Unit 1646

Ruixiang Li, Ph.D.
February 17, 2008